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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,359	07/15/2004	Domenico Fanara	2004_1045A	8158

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SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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11/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,359

Applicant(s)

FANARA ET AL.

Examiner

Lezah W. Roberts

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 10-14 and 23-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8, 10-14 and 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed July 31, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 1-3, 5-8, 10, 12-14 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen (US 2004/0028772) in view of Cherukuri et al. (US 4,238,510).

Andersen discloses a chewing gum composition comprising an active ingredient. The gum base comprises 15-99%, the active agent comprises 0.001-75%, optionally flavor up to 5%, optionally one or more high potent sweeteners 0.01-5%, optionally one or more solubilizers and bulk sweetener q.s. ad 100%, all w/w (paragraphs 0068-0074). Active agents include cetirizine (paragraphs 0110 and 0192). Bulk sweeteners include maltose, dextrin, hydrogenate starch hydrolysates and isomalt, which all have molecular weights over 300. The sweeteners may be used in combination. The chewing gums may also comprise solubilizers such as cyclodextrins that affect the release of medicinal substances. The chewing gums include a coating, which may include wax, a film coating or a conventional so-called candy coat based on sugar-containing or sugar free substances. Sugar sweeteners, which are considered sugarless, include mannitol and

starch hydrolysates (paragraph 0137). The coating may or may not comprise the active agent. The reference differs from the instant claims insofar as it does not specifically disclose the sugars or sugar-free components that can make-up the coating although it does disclose specific sweeteners fitting in these categories for use in the gum compositions in general.

Cherukuri et al. disclose sugarless coating for chewing gums. One coating comprises mannitol, calcium carbonate, and gelatin (col. 6, lines 20-30). The reference differs from the instant claims insofar as it does not disclose the gum center comprise an agent of Formula I.

It would have been obvious to one of ordinary skill in the art to have used the sugarless coating formulations as the coatings for chewing gums of the primary reference motivated by the desire to use a coating disclosed in the art as useful for chewing gums, candies and medicinal compositions, as disclosed by the secondary reference.

In regards to the cyclodextrin being beta cyclodextrin, it would have been obvious to use a cyclodextrin in the compositions of the primary reference motivated by the desire to use a cyclodextrin that is disclosed in the art as commercially available with a high purity and able to reduce degradation of pharmaceutical agents¹.

¹ Testa (US 5,866,179), col. 2, lines 12-63.

2) Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen (US 2004/0028772) in view of Cherukuri et al. (US 4,238,510) as applied to claims 1-3, 5-8, 10, 12-14 and 35-36 in further view of Hill (US 5,380,530).

The primary and secondary references, Andersen and Cherukuri et al., are discussed above. The references differ from the instant claims insofar as they do not disclose sodium citrate in the compositions.

Hill et al. disclose chewing gums that may comprise buffers such as sodium citrate. The reference differs from the instant claims insofar as it does not disclose the compositions comprise a compound of formula I.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. See Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used sodium citrate in the compositions of the primary reference motivated by the desire to use a compound for its known buffering function, as disclosed by the secondary reference and supported by cited precedent.

3) Claims 23-30 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,627,234).

Johnson et al. disclose coated chewing gum compositions where the coating or the coating and gum center comprise an active agent (col. 2, lines 62-64). The active agents include cetirizine hydrochloride (col. 6, line 50). Active agents may comprise 10 ppm to 30% of the chewing gum coating, encompassing the instant claims. The active agent may either be in a film coating or polyol/sugar coating. The coating may be a film coating comprising the active agent, which does not include a polyol as recited in the instant claims. Medicants may be dissolved in solvents, flavors and other transdermal vehicles. The coating also includes sweeteners such as sucrose, saccharin, saccharin salts, aspartame, sucralose and acesulfame-K, flavors and bitterness inhibitors such as sodium salts. Bulk sweeteners included in the chewing gum base include mannitol and hydrogenated starch hydrolysates. They comprise 5 to 95% of the gum. Softeners that may be used in the gum compositions include hydrogenated starch hydrolysates. Binders may be included in the chewing gum compositions and include gum arabic and alginate (cols. 12-14). The compositions also include agents such as calcium carbonate. The reference differs from the instant claims insofar as it does not disclose the core formulation comprising a polysaccharide and polyol such as mannitol in a composition together.

The reference is not anticipatory insofar as one must "pick and choose" from different lists of active agents softeners, binders and sweeteners. That being said, it would have been obvious in a self-evident manner to have selected cetirizine as a medicant from one list to use in a film coating, a polysaccharide such as starch from one list, and mannitol from another to use in the gum base, motivated by the

unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners.

4) Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,627,234) in view of Hill (US 5,380,530).

The primary reference, Johnson et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose sodium citrate in the compositions.

Hill et al. disclose chewing gums that may comprise buffers such as sodium citrate. The reference differ from the instant claims insofar as it does not disclose the compositions comprise a compound of formula I.

It would have been obvious to one of ordinary skill in the art to have used sodium citrate in the compositions of the primary reference motivated by the desire to use a compound for its known buffering function, as disclosed by the secondary reference and supported by Sinclair & Carroll Co. v. Interchemical Corp., In re Linder, and In re Dial, as cited above.

5) Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,627,234) as applied to claims 23-27, 29-30 and 32-34 in view of Kurihara et al. (US 5,344,659).

The primary reference Johnson et al. is discussed above. The reference differs from the instant claims insofar as it does not disclose the compositions comprise cyclodextrin.

Kurihara et al. disclose chewing gum compositions comprising film formers. The reference is used as general teaching to disclose different film formers that are used as coating agents in chewing gums. The film formers include gelatin and cyclodextrin. The reference differs from the instant claims insofar as it does not disclose the coating comprises a composition of Formula I.

It would have been obvious to one of ordinary skill in the art to have used cyclodextrin as film former in the coating of the primary reference motivated by the desire to use a compound for its desired film forming function. See Sinclair & Carroll Co. v. Interchemical Corp., In re Linder, and In re Dial, as cited above.

In regards to the cyclodextrin being beta cyclodextrin, it would have been obvious to use a cyclodextrin in the compositions of the primary reference motivated by the desire to use a cyclodextrin that is disclosed in the art as commercially available with a high purity and able to reduce degradation of pharmaceutical agents, see footnote above.

Claims 1-3, 5-8, 10-14 and 23-38 are rejected.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

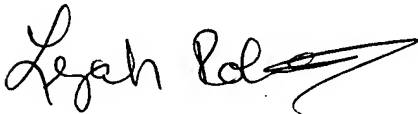
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

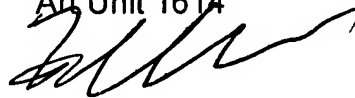
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read "Leah Roberts", with a stylized flourish at the end.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read "Frederick Krass", with a stylized flourish at the end.